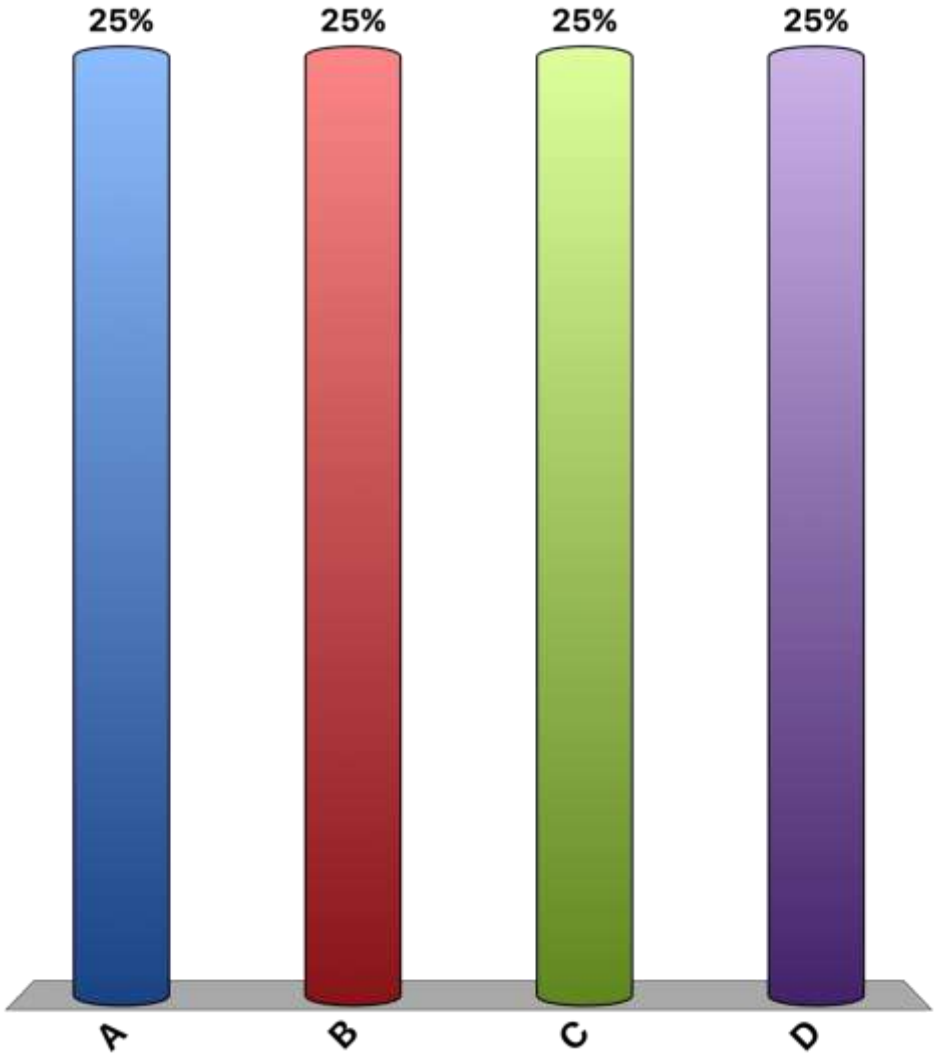
30 March 2016 Waterfront Meeting

	Speaker	Topic	Time
COMNAVSURFPAC	HMCS Coleman	General announcements	45
MRD-SD	LCDR Gutweiler	Pretest	5
NMCSD Infect. Disease	Dr. Stone-Garza	HIV Pre-exposure Prophylaxis	30
NMCSD Fleet Liaison	HM1 Merriman/HMC Sanchez	Medical Transition Company	20
MRD-SD	LT Hightower	Post Test	5
		Total	1:45

Pre-Test

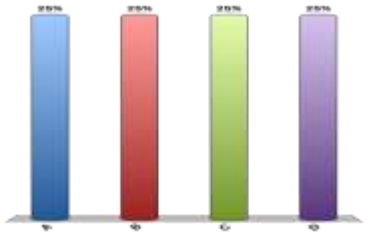
Clark Kent : Superman :: Bruce Wayne :

A. Hulk
B. Batman
C. Spiderman
D. Wolverine



What anti-retroviral medication is FDA approved for HIV pre-exposure prophylaxis (PrEP)?

A. Atripla (efavirenz, emtricitabine, tenofovir)
B. Combivir (lamivudine and zidovudine)
C. Truvada (emtricitabine/tenofovir)
D. Epzicom (abacavir sulfate/lamivudine)
E. Unsure



Per CDC guidelines, how often should HIV screening be performed after starting PrEP?

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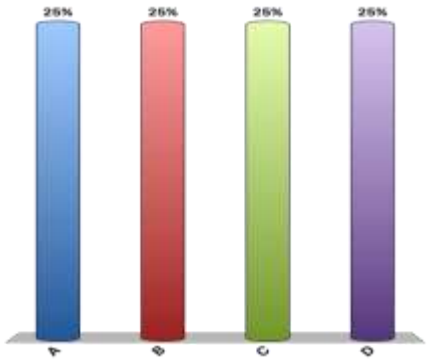
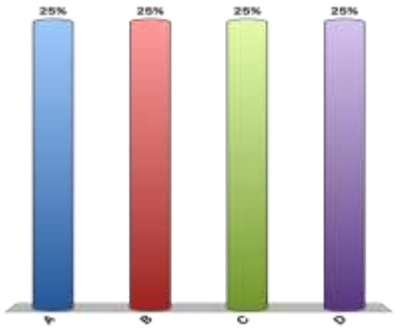


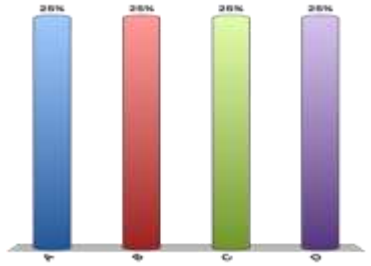
Per CDC guidelines, patients should be screened for the following prior to initiation of PrEP?

A. Hepatitis B infection
B. If female and child bearing age, screen for pregnancy
C. HIV
D. All of the above



What toxicity should be monitored while on PrEP?

A. Hepatotoxicity
B. Nephrotoxicity
C. Bone Marrow Suppression
D. Pulmonary toxicity
E. Unsure



NMCSD Infectious Disease

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HIV Pre-Exposure Prophylaxis (PrEP)

KRISTI STONE-GARZA, MD, MPH

LCDR MC USN

DIVISION OF INFECTIOUS DISEASES

NAVAL MEDICAL CENTER SAN DIEGO

DISCLOSURES

- Dr. Stone-Garza has no relevant financial relationships with any commercial supporters.
- Unlabeled/Investigational products and/ or services may be mentioned in this CME offering.
- Presentation adapted from
  - Brian Wood, MD. *Pre-Exposure Prophylaxis (PrEP) for HIV Prevention: 2015 Update.* 2015. Northwest AIDS Education and Training Center (NW AETC).
  - Katherine Marx, MS. *HIV Pre-Exposure Prophylaxis*. 2014. NY NY AIDS Education and Training Center.

LEARNING OBJECTIVES

- HIV/AIDS Facts
- Definition of PrEP
- Efficacy, risks and benefits of PrEP
- Who should we consider for PrEP
- Implementing and monitoring while on PrEP
- Referrals for PrEP

HIV FACTS

- According to World Health Organization (WHO), ~ 36.9 million worldwide living with HIV/AIDS
- In 2014, ~2 million new HIV infections diagnosed worldwide

http://www.cdc.gov/hiv/statistics/overview/ataglance.html
https://www.aids.gov/hiv-aids-basics/hiv-aids-101/global-statistics/

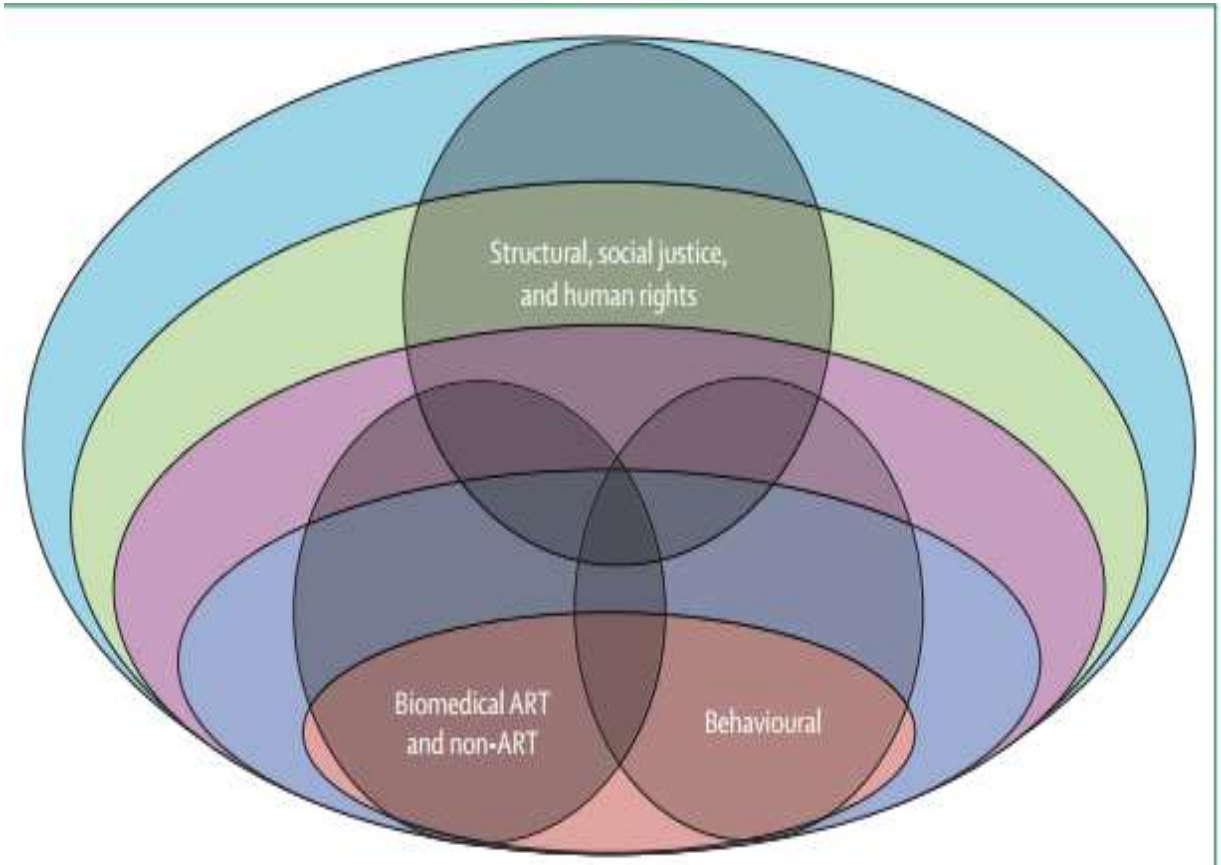
https://www.aids.gov/hiv-aids-basics/hiv-aids-101/statistics/index.html

AIDS FACTS

- In 2013, an estimated 47,000 people were diagnosed with HIV infection in the United States.
  - ~26,000 people were diagnosed with AIDS.
- ~1.1million people in the United States have been diagnosed with AIDS.

http://www.cdc.gov/hiv/statistics/overview/ataglance.html

HIV PREVENTION

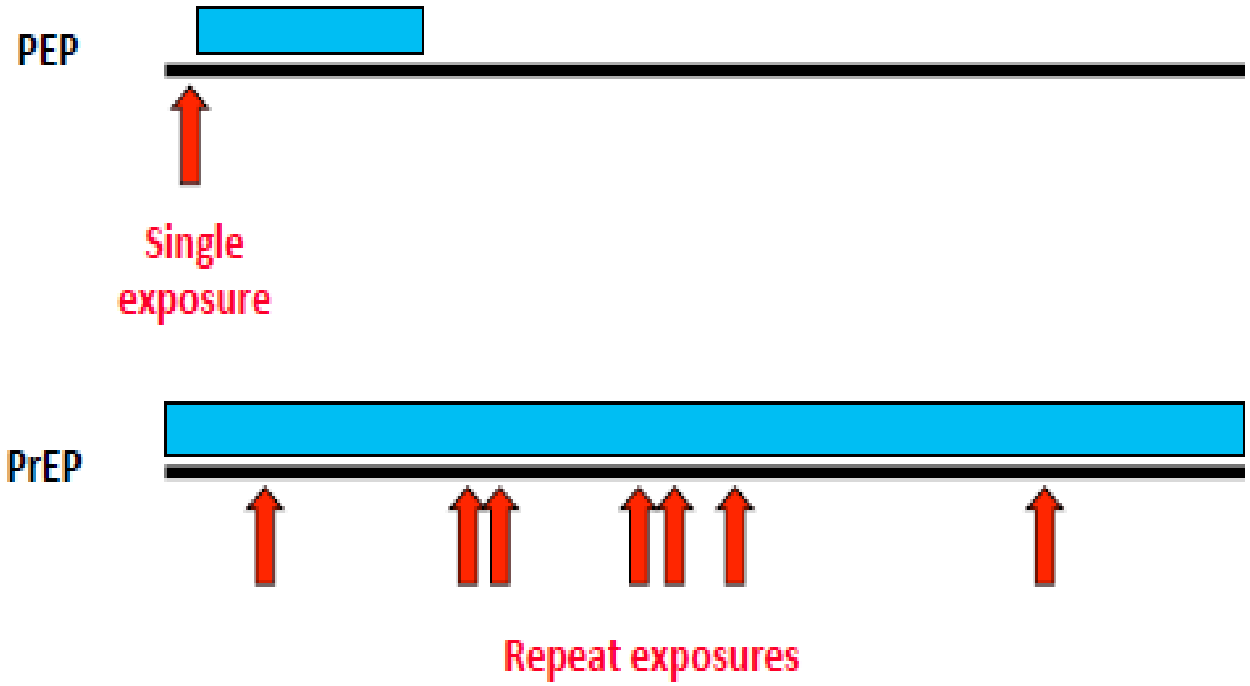


Level of risk	Indicator
Stage of epidemic	Prevalence and incidence
Public policy	Criminalisation, punitive laws, human rights contexts
Community	Community cohesiveness, sex-worker friendly services, voluntary counselling and testing, antiretroviral (ART) access, community-based structures, drug use programmes
Network	Sexual and physical violence, injection drug user networks, shared sex clients, HIV prevalence, HIV knowledge, gender-based violence
Individual	Unprotected anal and vaginal sex, multiple concurrent partners, substance misuse, gender-based violence, economic factors
Prevention intervention as part of highly active combination prevention	

Lancet. 2015 Jan 3;385(9962

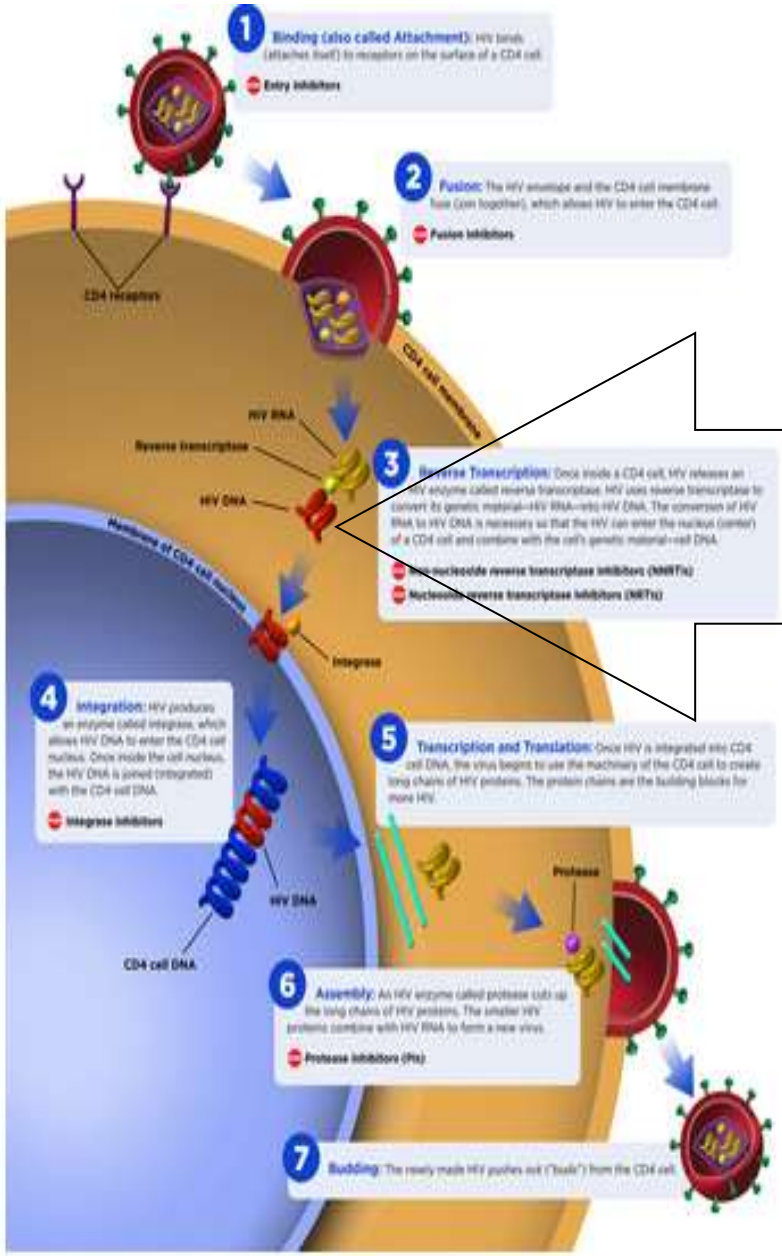
What is PrEP?

PEP VS PrEP



*Blue bar represents taking an HIV medication to prevent infection

Adapted from Dr. Brian Wood's presentation: Pre-Exposure Prophylaxis (PrEP) for HIV Prevention: 2015 Update; University of Washington, 2015



PrEP: Truvada (Tenofovir/emtricitabine) works here

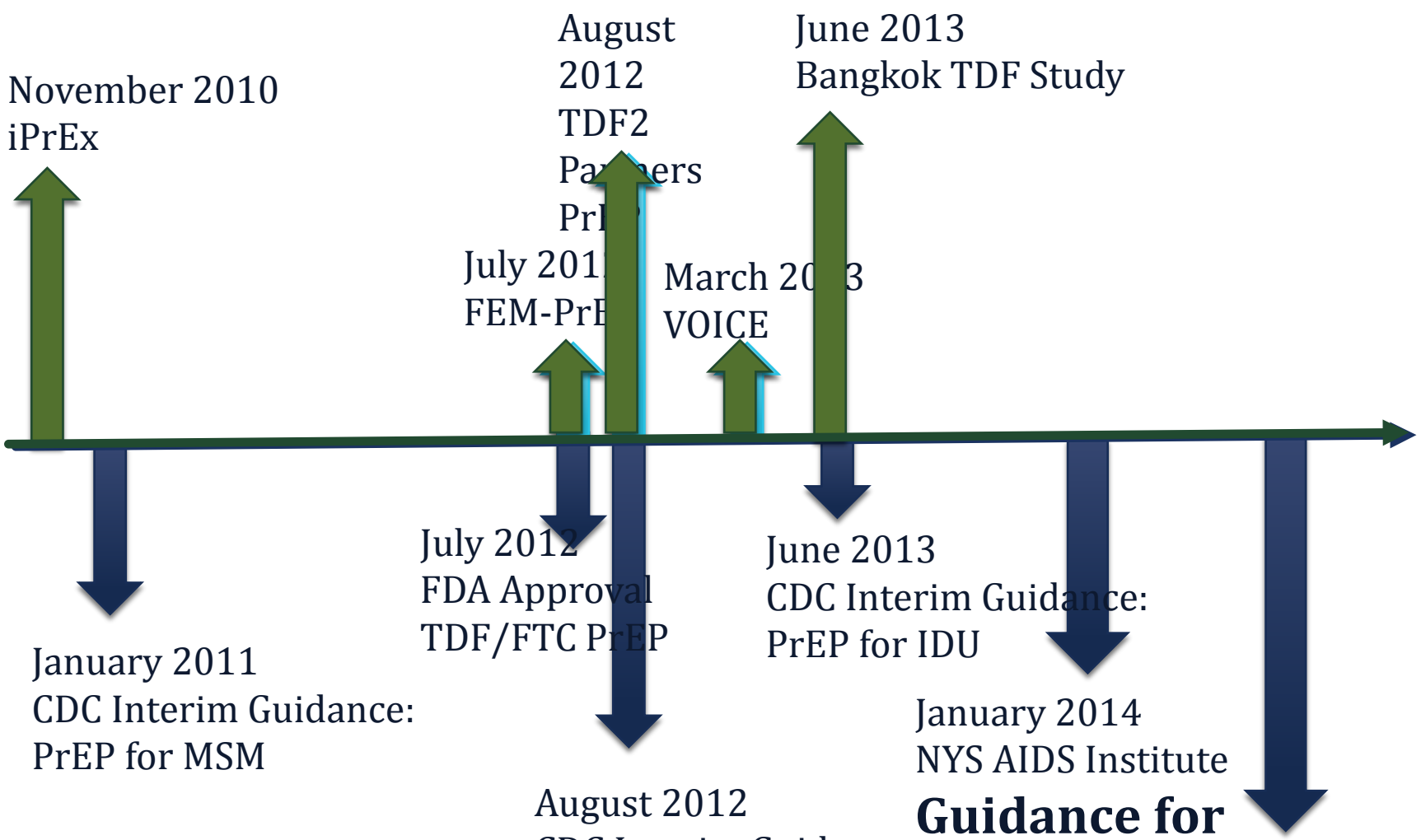
http://www.aidsinfo.nih.gov/education-materials/fact-sheets/19/73/the-hiv-life-cycle

TRUVADA® (TENOFOVIR/EMTRICITABINE)

- Antiretroviral, Nucleoside Reverse Transcriptase Inhibitor (NRTI)
- Active against HIV and Hepatitis B
- CrCl > 60 ml/min
- Side effects
  - Tenofovir: nausea and flatulence
  - Emtricitabine: rash, headaches
  - "Start-up syndrome"
  - < 10% and primarily during 1st month
- Bone mineral density: tenofovir associated with small change in bone mineral density but without increased risk of fracture

Image: http://www.usatoday.com/story/news/nation/2014/04/06/gay-men-divided-over-use-of-hiv-

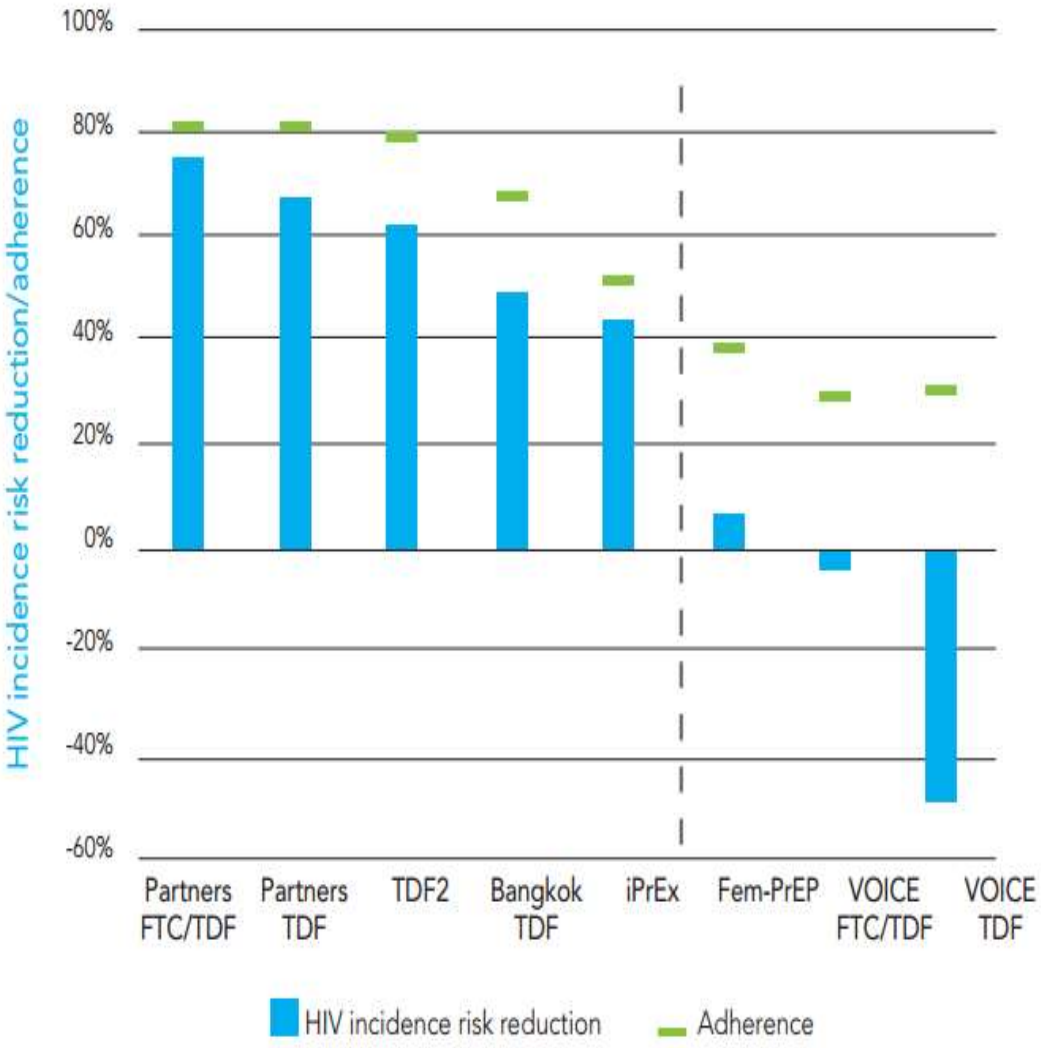
PrEP Timeline



Adapted from Katherine Marx presentation: PrEP - HIV Pre-exposure Prophylaxis. 2014

Is PrEP effective?

Figure 7. PrEP efficacy and adherence in major studies: PrEP works if taken



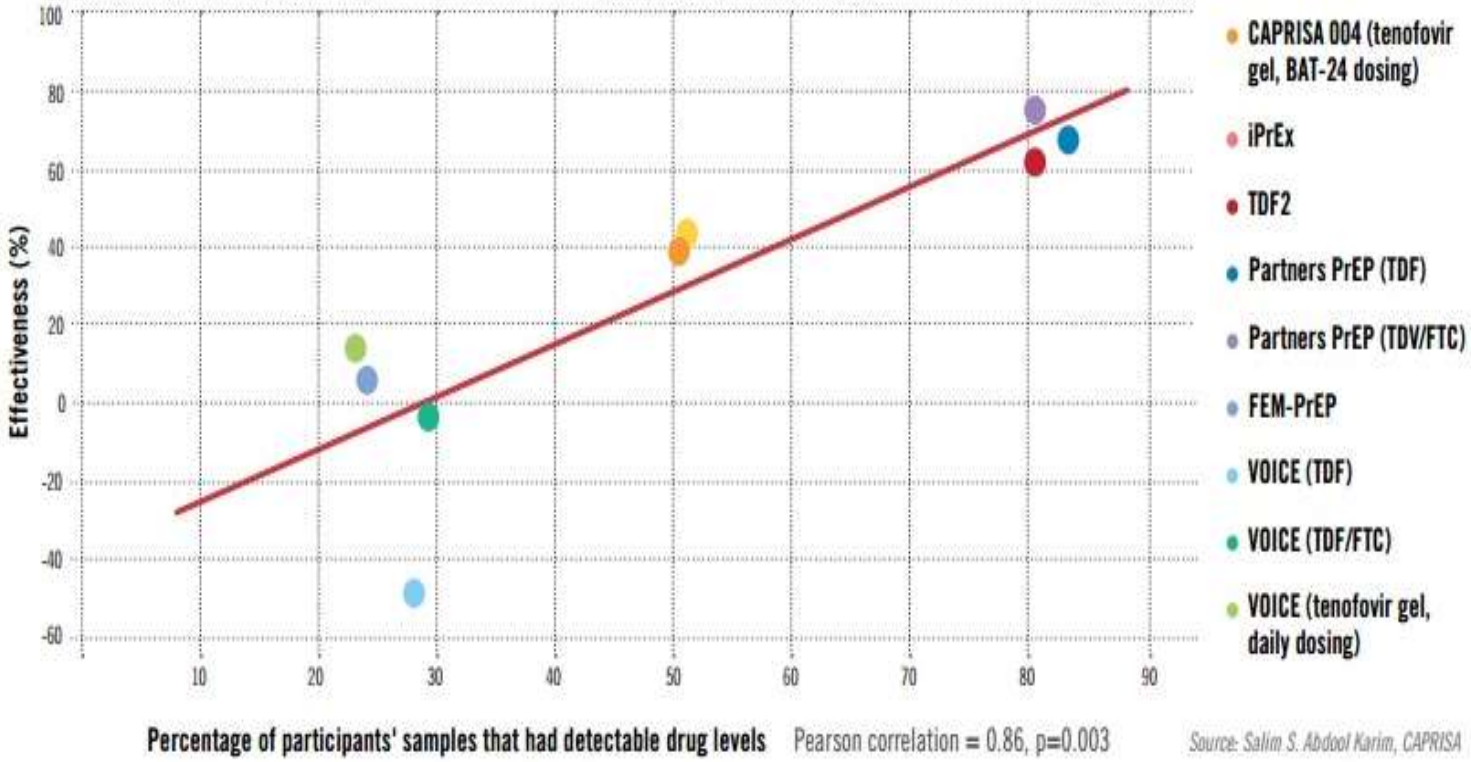
Source: Prepared based on WHO, 2015 (24).

http://www.avac.org/sites/default/files/resource-files/Fast-

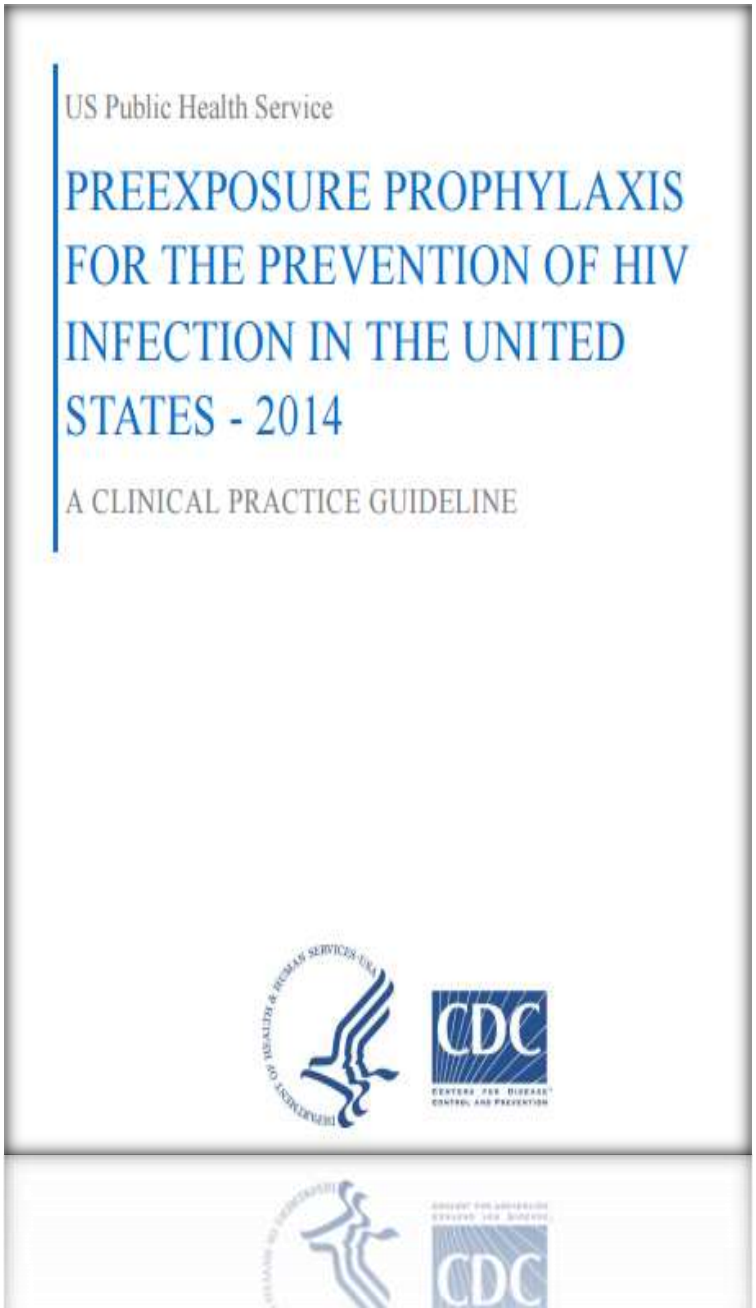
PrEP Works if You Take It — Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention

Trials of oral and topical tenofovir-based PrEP show that these strategies reduce risk of HIV infection if they are used correctly and consistently. Higher adherence is directly linked to greater levels of protection.

Calculations based on analyses involving a subset of total trial participants.



http://www.avac.org/sites/default/files/u44/PrEPWorks.jpg


US Public Health Service
PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014
A CLINICAL PRACTICE GUIDELINE
CDC

Who should take PrEP?

HIGH RISK POPULATION

Men who have sex with men (MSM)

- HIV-positive sexual partner
- Recent bacterial STI
- High number of sex partners
- History of inconsistent/no condom use
- Commercial sex work

http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

HIGH RISK POPULATION

Heterosexual women and men

- HIV-positive sexual partner
- Recent bacterial STI
- High number of sex partners
- History of inconsistent/no condom use
- Commercial sex work
- High-prevalence area or network

http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

HIGH RISK POPULATION

Injection drug users (IDU)

- HIV-positive injecting partner
- Sharing injection equipment
- Recent drug treatment (but currently injecting)

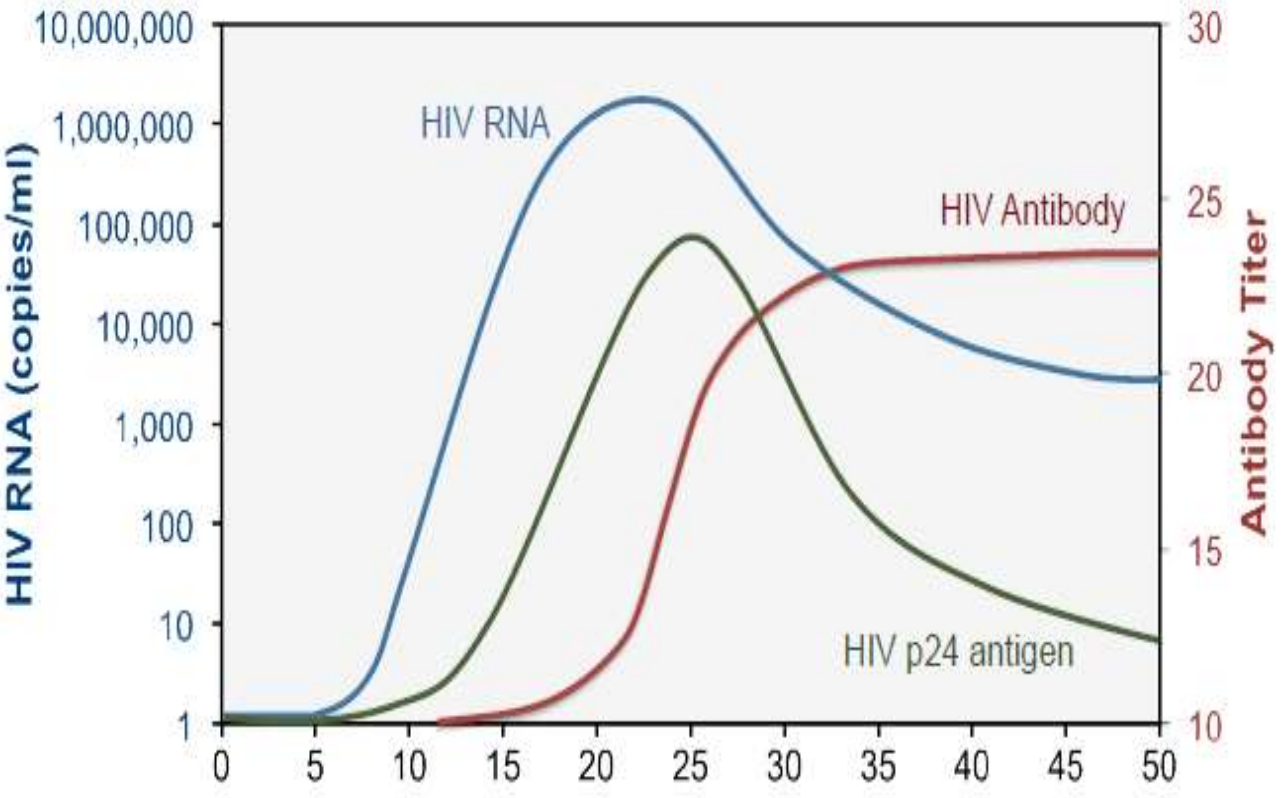
http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

Screening Prior to PrEP

CLINICAL ELIGIBILITY

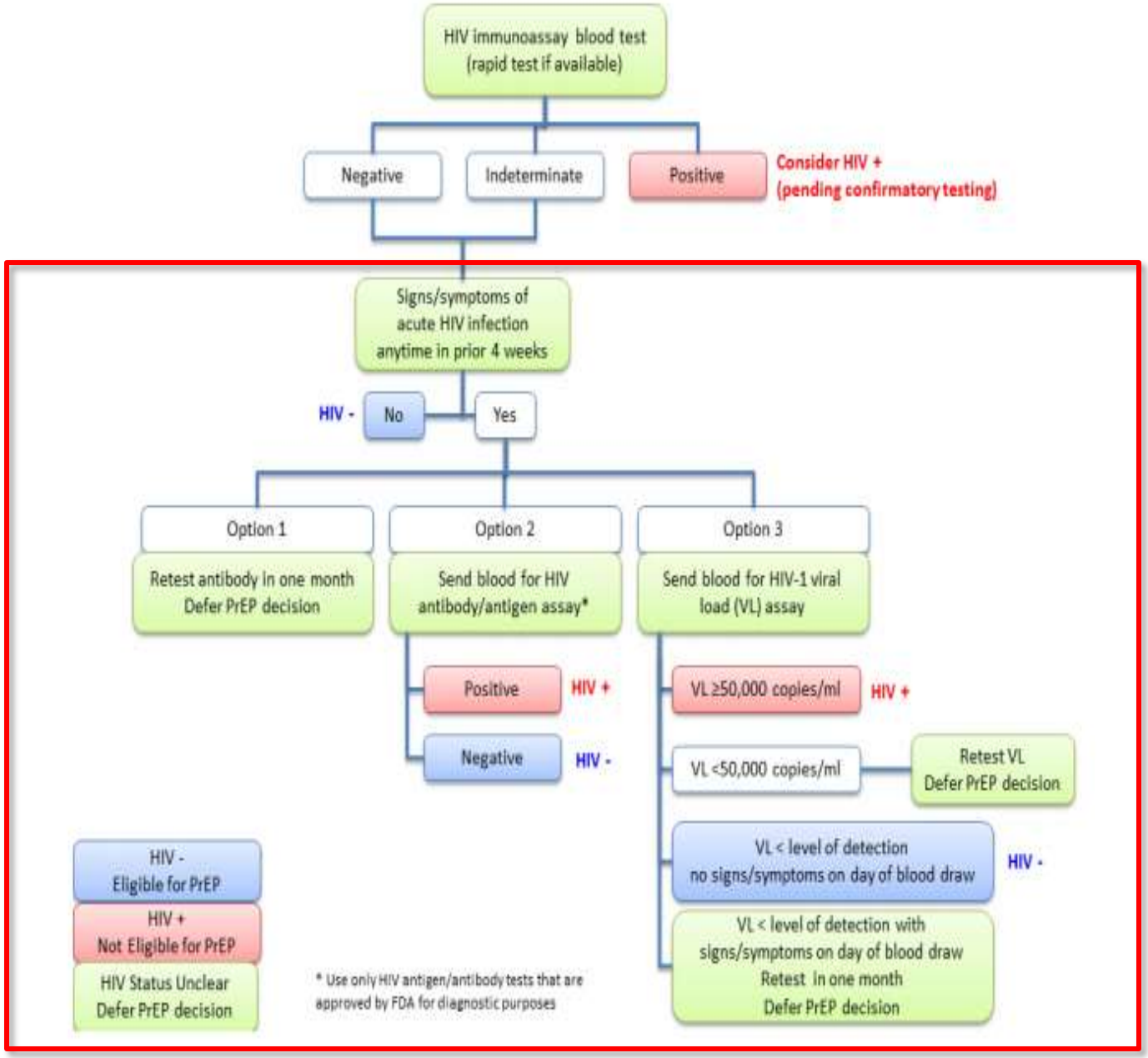
- Documented negative HIV test
- No signs/symptoms of acute HIV infection

LABORATORY DIAGNOSIS OF EARLY HIV INFECTION



Timing of HIV RNA, HIV p24 antigen, and HIV Antibody

Adapted from Dr. Brian Wood's presentation: Pre-Exposure Prophylaxis (PrEP) for HIV Prevention: 2015 Update; University of Washington,



http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

ACUTE HIV INFECTION

- Fever (75%)
- Fatigue (68%)
- Myalgia (49%)
- Skin rash (48%)
- Headache (45%)
- Pharyngitis (40%)
- Cervical Lymphadenopathy (39%)
- Arthralgia (30%)
- Night sweats (28%)
- Diarrhea (27%)

http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

CLINICAL ELIGIBILITY

- Documented negative HIV test
- No signs/symptoms of acute HIV infection
- Normal renal function (CrCl > 60 ml/min)
- No contraindicated medications
  - Acyclovir, valacyclovir, high dose or multiple NSAIDs
- Documented hepatitis B infection & vaccination status

OTHER CONSIDERATIONS

- Age
- Reproductive Age
- Osteopenia/osteoporosis

Good candidate for PrEP….now what?

PRIOR TO STARTING PrEP

- Determine of good candidate
- Clinically eligible with no contra-indications
- Educate:
  - Side effects
  - Limitation
  - Adherence
  - Symptoms of acute HIV
  - Monitoring schedule
  - Safety
  - Discontinuation
- Social history: substance abuse, mental health, etc
- Risk reduction counseling

PRESCRIPTION

Prescribe no more than 90-day supply of PrEP

- Truvada 1 tablet PO daily

(tenofovir 300mg + emtricitabine 200mg)

http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

MONITORING WHILE ON PrEP

3 month clinic visit

- HIV test
- Assess for acute infection
- Check for side effects
- Pregnancy testing (F)
- Prescribe 90-day supply of medication

http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

MONITORING WHILE ON PrEP

- Clinic visit every 3 months
- Every 3 month HIV test
- Every 3-6 month STI screening
- Renal function at 3 months and then every 3-6 months
- Assess pregnancy intent and check pregnancy every 3 months (F)

http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

Summary of Guidance for PrEP Use

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	• Sexual partner with HIV • Recent bacterial STD • High number of sex partners • History of inconsistent or no condom use • Commercial sex work	• Sexual partner with HIV • Recent bacterial STD • High number of sex partners • History of inconsistent or no condom use • Commercial sex work • Lives in high-prevalence area or network	• HIV-positive injecting partner • Sharing injection equipment • Recent drug treatment (but currently injecting)
Clinically eligible:	• Documented negative HIV test before prescribing PrEP • No signs/symptoms of acute HIV infection • Normal renal function, no contraindicated medications • Documented hepatitis B virus infection and vaccination status		
Prescription	Daily, continuing, oral doeses of TDF/FTC (Truvada), ≤90 day supply		
Other services:	• Follow-up visits at least every 3 months to provide: • HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment • At 3 months and every 6 months after, assess renal function • Every 6 months test for bacterial STDs		
	• Do oral/rectal STD testing	• Assess pregnancy intent • Pregnancy test every 3 months	• Access to clean needles/ syringes and drug treatment services

Source: US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States —2014: a clinical practice guideline.

DISCONTINUING PrEP

- Positive HIV result
- Acute HIV signs or symptoms
- Non-adherence
- Renal disease
- Changed life situation: lower HIV risk

http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

How can patient's obtain PrEP?

PrEP

- Requires Infectious Diseases evaluation
- Medication restricted to Infectious Diseases
- Self-referral for PrEP consult
- NMCSD ID Clinic: 619-532-7475
- Pre-appointment labs
- Appointment
- PCP follow up/ monitoring?????

THANK YOU…….QUESTIONS?

Contact Info:

Kristi Stone-Garza, MD, MPH

LCDR MC USN

Division of Infectious Diseases

Naval Medical Center San Diego

Phone: 619-251-8552

Fax: 619-532-7478

Email: Kristi.k.stonegarza.mil@mail.mil

Medical Transition Company (MTC) POC Information

LT Myra Wearing, DIVO
619-532-7736 / 619-279-4850
HMC Rose Sanchez, MTC LCPO
619-532-5390 / 619-730-9878
HM1 Patrick Merriman, MTC LPO
619-532-5390 / 757-537-6349
HM2 Emily Burgess, MTC ALPO
619-532-5390 / 757-537-6349

MTC Front Office
619-532-9928
MTC After-Hours Duty
619-453-6005

Medical Transition Company

Naval Medical Center San Diego

NAVAL MEDICAL CENTER
SAN DIEGO
THE PRIDE OF NAVY MEDICINE

Purpose

* To provide berthing and administrative cognizance until NMCSD provider determines the disposition of the Sailor's Care.
* Within 60 days of arrival to MTC, NMCSD provider must Decide:
  * Return to Duty
  * LIMDU
  * Medboard

What is the MTC

* MTC is a barracks for Sailors from operational or geographically distant commands receiving frequent outpatient treatment at NMCSD.
* While at MTC, patients:
  * Live in BLDG 26 / (or home)
  * Muster four times a day
  * Assigned Light Duty work
* MTC Staff is tasked with ensuring both the wellbeing and good order / discipline of MTC residents

* The MTC is **NOT** a step-down facility
  * Patients must be:
    * Ambulatory
    * Fully capable of self-care
    * Require no dietary care
    * Require no other special treatment
      * Wound flush, dressing changes, infusions, etc
  * No patient care is performed in MTC
    * No special musters / bed checks / monitoring

Who Qualifies for MTC?

* Enlisted Sailors are assigned to MTC to complete outpatient medical treatment or wait IDES processing
  * Operational Commands: Ships, Squadrons, FMF, etc
  * Command Outside Geographic Area: Level 5 Care
* DoD physician written order required (to include NAVMED 1306/1 Assignment to Medical Transition Company form)
* Recovery expected within 60 days:
  * If expected longer: LIMDU or MEB required

Who Doesn't Qualify for MTC?

* Shore Commands!
  * If stationed within NMCSD's geographic area:
    * Must return to Parent Command while receiving outpatient treatment
* Exceptions:
  * Mental Health:
    * "psychiatrist determines that the return to the parent command would aggravate their condition regardless of the location of the parent command"

Exceptions

* Final Determination made by MTC OIC
  * MTC OIC will consult with the following:
    * Treating Physician
    * Parent Command
  * MH: Usually only those in Dr. Tuttle's PTP.
* Shore Command / Provider relations
  * Common Issues:
    * Mustering, Working, Reporting Appointments, etc
  * Often can be resolved between CoC / Provider

Patient Movement for LIMDU

- Sent TAD from Parent to NMCSD for evaluation
- Berthing / Admin through NMCSD MTC
- Placed on LIMDU by Mental Health
- Launched from MTC to TPU
- TPU / BUPERS assigns to local shore command
  - LIMDU orders
  - Allows continuation of treatment at NMCSD
    - Yes: TPU has a duty van

Patient Movement for IDES

- Sent TAD from Parent to NMCSD for evaluation
- Berthing / Admin through NMCSD MTC
- Placed on Medboard by Mental Health
- Remains in NMCSD MTC until Medboard is mailed
- Launched from MTC to TPU
- Depending on IDES results:
  - TPU separates or returns to duty the Sailor

Accepting Patients

When accepting patients from other commands:

* Submit Consult (SF513) via email to Operational Forces Medical Liaison Office (OFMLO):

  NMCSD.FLMO@med.navy.mil

* OFMLO:
  * Liaisons with Parent Command
  * Schedules any additional necessary appointments
  * Coordinates berthing with NMCSD MTC

Contact Information

* LT Myra Wearing, DIVO – 619-532-9932
* HMC Rose Sanchez, LCPO – 619-532-5390
* HM1 Patrick Merriman, LPO – 619-532-5390
* HM2 Emily Burgess, ALPO – 619-532-5390
* MTC Admin Office – 619-532-9928
* MTC Duty Cell – 619-453-6005

Medical Readiness Division

MRD_SD_GMO@navy.mil

(619) 556-5191

Bldg 116

San Diego, CA 92136

Upcoming Meetings

- **April 27th** @ 1000-1200
  - Wound Care/Skin Closure/Suturing/Local anesthesia/digital block
  - Mind Body Medicine
- **May 25th** @ 1000-1200
  - GI bleed/DRE/Prostatitis

CME Information

- CME Code (To claim credit online): **8287**
- Closing Date (To claim credit online): **06 APR 2016**
- To complete CME
  - Log onto the MRD IDC website and click on the CME credit link

    or
  - Go to NMCSD SEAT SharePoint site (via citrix or NMCSD/BMC computer) and click on MRDSD Waterfront Meeting

http://nmcsd-as-spfe05/sites/dpe/setd/Lists/cmesurvey/Item/newifs.aspx?List=be0f840e%2D0489%2D4b5a%2Db8de%2D9c4cd1a323e5&Web=0901130e%2Dd444%2D45b8%2D8bc7%2D5b9ec10dca77

Post-Test

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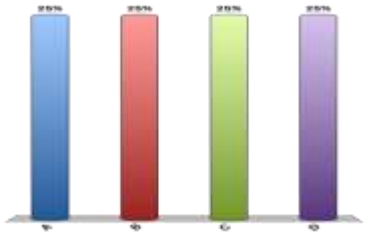

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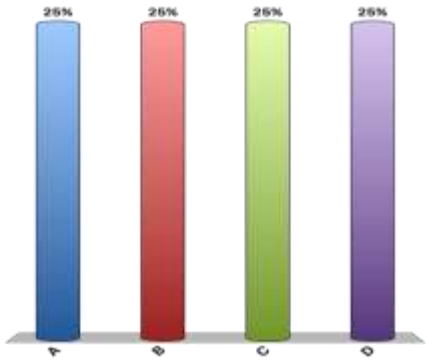
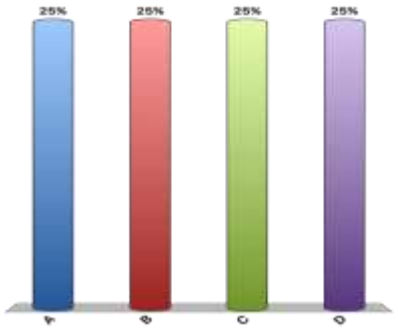


Per CDC guidelines, patients should be screened for the following prior to initiation of PrEP?

A. Hepatitis B infection
B. If female and child bearing age, screen for pregnancy
C. HIV
D. All of the above



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B. Nephrotoxicity
C. Bone Marrow Suppression
D. Pulmonary toxicity
E. Unsure